

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Forbes Jones et al.	:	
	:	COBALT-NICKEL-CHROMIUM-
Group Art Unit 1742	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF TITANIUM
Serial No. 10/656,918	:	NITRIDE INCLUSIONS
	:	
Filed September 5, 2003	:	
	:	Confirmation No. 8375
Examiner Jessee Roe	:	

DECLARATION OF HENRY E. LIPPARD, Ph.D.

Pittsburgh, Pennsylvania 15222-2312
August 23, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Henry E. Lippard, declare as follows:
2. I am a citizen of the United States and currently reside at 9810 Edinburgh Lane, Charlotte, North Carolina.
3. I am over the age of eighteen and am competent to make the statements in this Declaration.
4. I obtained my Bachelor of Science in Materials Science and Engineering from North Carolina State University in 1992, and my Ph.D. in Materials Science and Engineering from Northwestern University in 1999.
5. I have been employed by ATI Allvac, a business unit of Allegheny Technologies Incorporated, located in Monroe, North Carolina, since July, 1997. My current position with ATI Allvac is Manager – Raw Materials and Nickel-base Primary Melting. Through my educational background and my employment at ATI Allvac I have

gained substantial experience and familiarity with alloy melting and other alloy preparation techniques including techniques for influencing alloy microstructure and properties. I have particular experience in the preparation of nickel-base alloys and other high performance non-ferrous alloys.

6. I am named as an inventor on the above-identified U.S. patent application ("the Application"). I am thoroughly familiar with the Application and the claims currently pending in the Application as amended in the Response accompanying this declaration. I also am thoroughly familiar with the alloy described in the Application and, in particular, am thoroughly familiar with a commercially available embodiment of the alloy described in the Application, which is sold by my employer, ATI Allvac.

The History of the Invention Described in the Application

7. Prior to the invention of the alloy described in the Application, a need existed for many years for biocompatible small diameter MP35N-type alloy wire having improved fatigue resistance. Cardiac pacemaker and defibrillator leads and certain other components of surgically implanted medical devices are commonly made from small diameter MP35N alloy wire. A known problem with MP35N alloy is that surface defects appear on wire drawn from the alloy. These surface defects tend to appear late in the wire production process, after substantial time and money has been invested in the product. The surface defects may cause the wire to fracture during the drawing process, which resulted in reduced product yield and increased the commercial cost of the wire. Also, pacemaker leads and certain other surgically implanted components formed from MP35N alloy wire having the surface defects were susceptible to fracture from fatigue, reducing in-service life and requiring premature replacement of the implant.

8. My co-inventors and I ("we") undertook to address these problems. In the course of this research we discovered that generally large, cuboidal titanium nitride and mixed metal carbonitride inclusions present in conventional MP35N alloy were scoring the surfaces of drawing dies used to draw the alloy to small-diameter wire. We further discovered that the surface defects discussed above were formed when wire is drawn through dies damaged by the inclusions. The surface defects manifested as scratches

on the wire surface that can hasten fatigue-induced fracture of the wire. We also discovered that as the wire diameter becomes smaller during drawing, nitride and carbonitride particles occupied an increasingly larger fraction of the wire cross-section, thereby weakening the wire and resulting in fractures during drawing. We further discovered that the cuboidal inclusions act as points of localized stress during fatigue loading and contribute to fatigue crack initiation, which can result in premature wire failure.

9. In an attempt to address the observed microstructural deficiencies in MP35N alloy, we experimented with modifications to the chemistry of conventional MP35N alloy. We surprisingly discovered that modifying the existing alloy chemistry to limit nitrogen to extremely low levels, less than 30 ppm, reducing titanium to less than 0.7 weight percent, and including certain small concentrations of at least one of aluminum, calcium, magnesium, or cerium resulted in an alloy with a fundamentally different microstructure – the microstructure substantially lacked cuboidal titanium nitride and mixed metal carbonitride inclusions and, instead, included relatively small, generally spherical oxide inclusions. We observed that the relatively small, generally rounded oxide inclusions are well tolerated by (*i.e.*, would not heavily score) the wire drawing equipment, substantially reducing the incidence of wire surface defects, and are much less likely to concentrate stresses in the wire to a degree resulting in wire fracture during drawing or when subjected to fatigue over time.

10. The very substantial change in microstructure produced by the chemistry modifications we made was entirely unexpected and very significant. The change was not merely a slight adjustment to microstructure, but unexpectedly resulted in a fundamentally different and well tolerated microstructure. Fortunately, the new microstructure of the alloy directly addressed the microstructural problems in the conventional MP35N alloy.

11. As discussed in detail in the Application, an apparent result of the above-discussed fundamentally different microstructure of the small-diameter wire produced from the alloy described in the Application exhibits very substantially improved fatigue resistance relative to conventional MP35N alloy. Table 9 of the Application, for

example, shows that at 100 ksi, a stress level similar to that to which cardiac pacemaker leads are subjected in service (*i.e.*, implanted in the body), wire formed from the alloy described in the Application withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy, and the modified alloy had a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy. This improvement in fatigue properties was very significant, was surprising to me and my co-inventors, and was not expected even after we observed the fundamentally altered microstructure of the alloy of the Application. The unexpectedly significantly improved fatigue resistance of the modified alloy directly addressed the above-mentioned long felt need in the medical device industry for a biocompatible MP35N-type alloy useful for pacemaker leads and other surgically implanted components having a reduced incidence of fatigue-induced fracture.

Smith U.S. Patent No. 3,356,542

12. I have thoroughly reviewed U.S. Patent No. 3,356,542 issued to Smith ("Smith"). Smith does not describe or suggest an alloy that includes less than 30 ppm of nitrogen. Although Smith does state that the alloy described in that patent should include "no more than 0.05%" nitrogen, that level is more than 15 times the maximum nitrogen level critical to the invention described in the Application. Smith does not describe or suggest that there is any benefit whatsoever to limiting the nitrogen level in the alloy of that patent to less than 30 ppm, or even to very small, ppm range, concentrations.

13. Given that Smith does not state or suggest that that the alloy in that patent has or would benefit from having less than 30 ppm nitrogen, or even very low (ppm range) nitrogen levels, the alloy of Smith would certainly have included at least 50 ppm nitrogen. For example, 50 ppm is the minimum level of nitrogen found in conventional MP35N alloy. Although Smith does refer offhand to vacuum melting, such techniques were well known at the time, and Smith does not state or suggest that melting under vacuum should be done for reducing alloy nitrogen levels or otherwise. Smith does not state or suggest any reason why one would have undertaken the involved, time-

consuming, and costly steps necessary to limit nitrogen in the alloy described in Smith to less than 30 ppm or to any other extremely low level.

14. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure could not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Also, Smith does not specifically describe or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

Thielmann U.S. Patent No. 3,241,954

15. I have thoroughly reviewed U.S. Patent No. 3,241,954 issued to Thielmann ("Thielmann"). I conclude that Thielmann is directed to alloys that differ significantly from the alloys described in Smith. I reach this conclusion based on the fact that the Smith and Thielmann alloys differ in at least the following ways:

- The Thielmann alloy lacks any appreciable level of molybdenum, while the Smith alloy includes 7-16% molybdenum.
- The Thielmann alloy includes 4-16% tantalum, while the Smith alloy lacks any appreciable level of tantalum.
- The Thielmann alloy includes 5-15% tungsten, while the Smith alloy lacks any appreciable level of tungsten.
- The Thielmann teaches that its alloy must not include more than 3.5% nickel, while the Smith alloy includes 5-45% nickel.
- The Thielmann alloy includes 0.1-1.3% carbon, while the Smith alloy includes no more than 0.05 % carbon.

16. The above differences are so significant that it is not correct to conclude that Thielmann teaches "an analogous cobalt-base alloy" relative to Smith. Instead, the alloys differ so substantially that one would not consider Thielmann pertinent when seeking out prior art relevant to modifying the properties of the alloy described in Smith.

Crook U.S. Patent No. 4,353,742

17. I have thoroughly reviewed U.S. Patent No. 4,353,742 issued to Crook ("Crook"). I conclude that Crook is directed to alloys that differ significantly from the alloys described in Smith. I reach this conclusion based on the fact that the Smith and Crook alloys differ in at least the following ways:

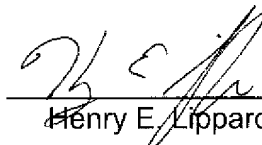
- The Crook alloy includes 27-35% chromium, while the Smith alloy includes 13-25% chromium.
- The Crook alloy may include up to 0.3% boron, while the Smith alloy includes no more than 0.05% boron.
- The Crook alloy may include up to 2.25% carbon, while the Smith alloy includes no more than 0.05% carbon.

18. The above differences are so significant that it is not correct to conclude that Crook teaches "an analogous cobalt-base alloy" relative to Smith. Instead, the alloys differ so substantially that one would not consider Crook particularly pertinent when seeking out prior art relevant to modifying the properties of the alloy described in Smith .

* * * *

19. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Date: 08/24/2007


Henry E. Lippard